3M Science. Applied to Life.™

3M™ Clinpro™ Tooth Crème

0.21% Sodium Fluoride Anti-Cavity Toothpaste

Technical Product Profile

Table of Contents

Background

Teeth are naturally covered by biofilm. Some bacteria contained in dental biofilm, once attached to the tooth, produce acids that dissolve tooth enamel and can ultimately lead to tooth decay.[1]

Demineralization occurs when the building blocks of teeth—calcium and phosphate—are dissolved by acid.[2] The process of demineralization may at first go unnoticed but will eventually result in a white spot lesion. A white spot lesion is the first visible sign of demineralization and is considered one of the first stages of tooth decay.[3]

Saliva serves as the body's natural defense against tooth decay by providing both physical and metabolic protective mechanisms. Saliva protects the tooth by clearing debris and acids from the tooth surface and by buffering acids produced in the mouth.[4] Saliva naturally contains calcium and phosphate that replace the minerals dissolved from teeth during the demineralization process.[3]

Saliva is also a carrier of fluoride.[3] Fluoride, calcium and phosphate come together on the tooth surface to form fluorapatite in a process called remineralization. Tooth surfaces made up of fluorapatite are harder and more resistant to acid than naturally occurring tooth surfaces, which are made of hydroxyapatite.[5]

The amount of naturally occurring fluoride in saliva is quite low. The scientifically proven, beneficial effects of fluoride have prompted the addition of fluoride to drinking water, toothpastes, rinses, gels and other topically applied products. Topical application of fluoride can raise the concentration of fluoride in saliva up to a thousandfold.[6]

Dental decay rates have decreased dramatically in many parts of the world over the past 60 years due to community water fluoridation, increased oral hygiene awareness and the use of fluoride-containing toothpastes. Fluoride delivery through community water fluoridation and fluoridated toothpaste has been shown to be a cost-effective public health measure for preventing tooth decay.[7]

Summary of advantages

- Contains 0.21% NaF (950 ppm fluoride ion)
- Can recharge fluoride-releasing dental materials with fluoride
- Protects against cavities and helps reverse white spots
- Contains functionalized tri-calcium phosphate (fTCP)
- Cleans and whitens teeth with low abrasion
- Perfect for pediatric patients at moderate or high risk for caries
- One-step convenience improves patient compliance
- Proven through 10 years of clinical usage
- Low sodium lauryl sulfate compared to other commercially available toothpastes

Product Description

3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste with functionalized tri-calcium phosphate (fTCP) was developed for patients who need the benefits of fluoride, calcium and phosphate daily. It contains 950 ppm fluoride ion and an innovative fTCP ingredient. This non-prescription-strength formula is intended for daily use and can be applied to enamel and exposed dentin to help remineralize demineralized tooth structure and aid in the prevention of tooth decay. Clinpro Tooth Crème toothpaste has a pH of 7 during normal toothbrushing.

Indications

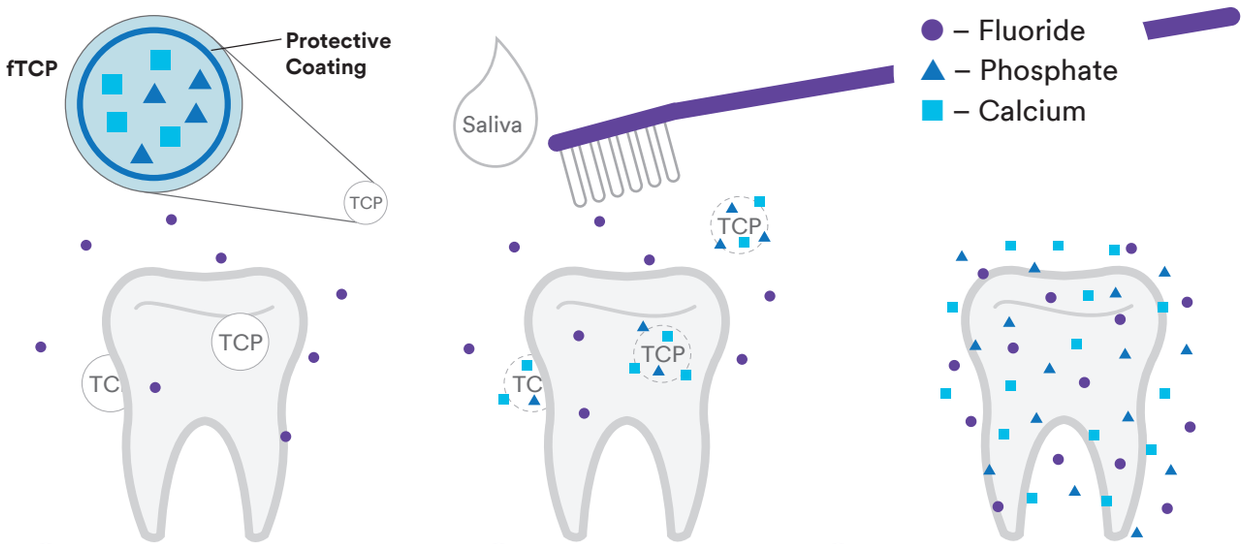
Clinpro Tooth Crème toothpaste is indicated for use as part of a professional program for the prevention and control of dental caries.

Composition

3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste contains 0.21% sodium fluoride and an innovative tri-calcium phosphate ingredient available exclusively from 3M. Each gram of Clinpro Tooth Crème contains 0.95 mg of fluoride ion in a neutral pH base consisting of water, sorbitol, hydrated silica, glycerin, polyethylene-polypropylene glycol, flavor, polyethylene glycol, sodium lauryl sulfate, titanium dioxide, carboxymethyl cellulose, sodium saccharin and tri-calcium phosphate.

Functionalized Tri-calcium Phosphate

Clinpro Tooth Crème contains an innovative tri-calcium phosphate (fTCP) ingredient available exclusively from 3M. Calcium and phosphate in the form of fTCP are added to enhance the naturally occurring mineral content of saliva necessary for building strong teeth. The fTCP ingredient includes a protective coating on the minerals to ensure the calcium and fluoride do not combine prematurely. When fTCP is exposed to saliva, the protective coating dissolves, allowing the calcium and phosphate to be released together with fluoride ions. When fluoride, calcium and phosphate are released together, they have a better chance of combining to form strong tooth mineral.



1. **A protective coating around calcium and phosphate prevents early interactions with fluoride.**
2. **During brushing, saliva breaks down the coating.**
3. **Calcium and phosphate are released, making them available directly at the tooth surface along with fluoride.**

Directions for Use

Adults and children 2 years and older: Brush teeth thoroughly after meals or at least twice a day, or use as directed by a dentist.

- Do not swallow. To minimize swallowing, use a pea-sized amount in children younger than 6 years of age.
- Supervise children's brushing until good habits are established.
- For children younger than 2 years of age, ask your dentist.

Evaluations and Studies

Fluoride Uptake

While the concentration of fluoride in a preparation is important, the amount of fluoride that is delivered to the demineralized tooth structure is equally important. *In vitro* laboratory testing was conducted to determine the fluoridating efficiency of 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste compared to that of other fluoride-containing preparations.

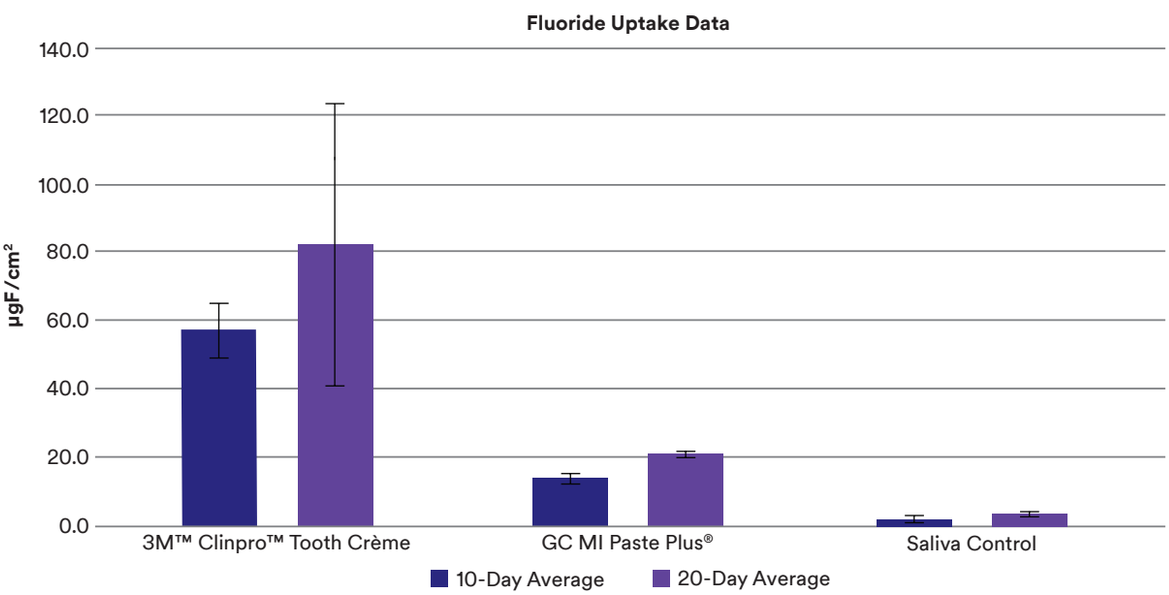
Methodology

Bovine teeth were cut, potted and polished. Samples were demineralized with a Carbopol®/lactic acid solution to form subsurface enamel lesions. Samples received four, 2-minute treatments of either Clinpro Tooth Crème toothpaste, GC MI Paste Plus® or artificial saliva daily followed by artificial saliva wash for 1 hour. Samples received a 4-hour acid challenge daily between the first two and second two treatments, and sat in an artificial saliva solution overnight. There was no rinsing after treatments.

A microdrill biopsy was taken to measure fluoride uptake into the enamel samples after 10 days and 20 days of treatment. The fluoride level after treatment was compared to the fluoride level before treatment to determine fluoride uptake.

Results

Clinpro Tooth Crème toothpaste exhibited statistically significantly greater fluoride uptake than GC MI Paste Plus® or the saliva control.



Source: 3M internal data

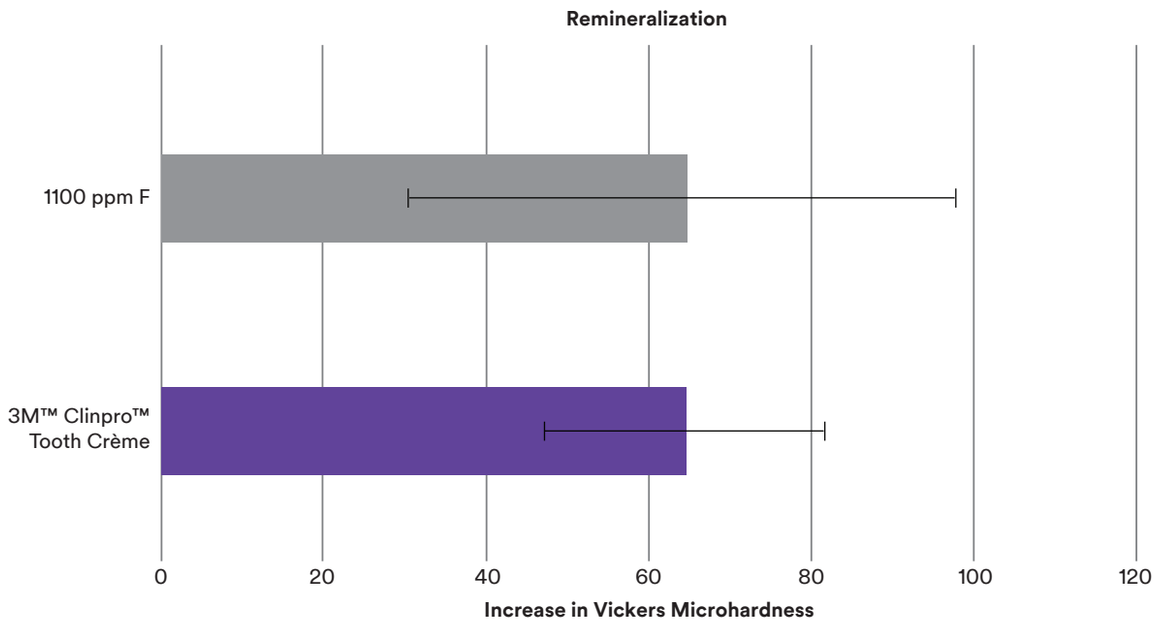
Remineralization

Methodology

Human enamel specimens were prepared and demineralized to form white spot lesions and evaluated for baseline Vickers microhardness. These specimens were then attached to a maxillary molar in 38 subjects with light-cured composite material. Study subjects participated in a 4-week, single-blinded, crossover study with 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste and a commercially available 1100 ppm toothpaste. Subjects brushed their teeth with their first assigned toothpaste for 4 weeks. After a 1-week washout period, a new enamel sample was placed, and the second assigned toothpaste was used for the next 4 weeks. The coded samples were then removed and analyzed for microhardness and fluoride content.

Results

In this clinical study, Clinpro Tooth Crème toothpaste exhibited remineralization and enamel fluoride uptake similar to an over-the-counter, 1100 ppm sodium fluoride toothpaste, despite having 150 ppm less fluoride.[8]



Source: Roopa, Pathak, Poornima, & Neena

Treatment of White Spot Lesions

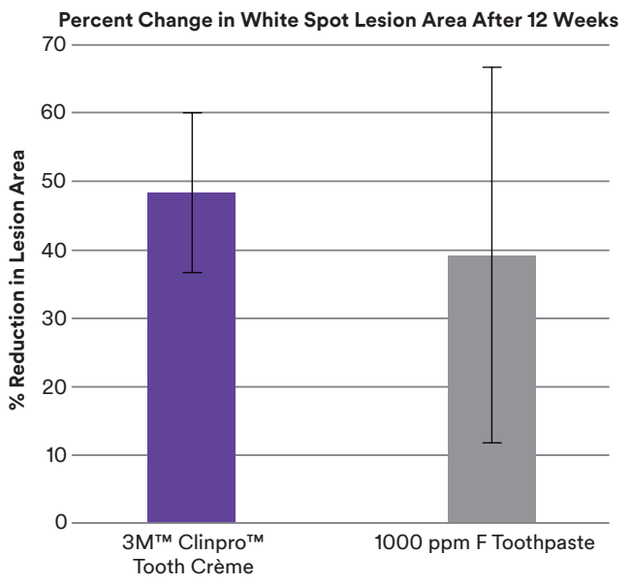
White spot lesions are an early sign of tooth decay that, if left untreated, will progress to frank caries lesions. Treatment of these demineralized areas with fluoride can stop progression and reverse the decay process through remineralization.[9]

Methodology

Nineteen healthy participants, with demineralized white spot lesions at orthodontic debonding, were randomly assigned to either a sodium fluoride toothpaste (950 ppm F), which contains fTCP (3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste), or a sodium fluoride toothpaste (1000 ppm F). They were instructed in toothbrushing technique, with a soft bristle toothbrush, using modified Bass technique twice a day. In each brushing, they brushed for 2 minutes and rinsed in 20 mL of tap water. They were also advised to consume less sugar-containing snacks or beverages with no more than two between meals, per day. Photographs of demineralized areas were taken before and after intervention at 4, 8 and 12 weeks, respectively. The areas before and after intervention, as well as percent area changes, were compared.

Results

In this clinical study, Clinpro Tooth Crème toothpaste provided a statistically significant reduction in the size of white spot lesions at 12 weeks after orthodontic debonding.[10]



Source: Limvirat, Nakornchai, Surarit, & Anuwongnukroh

Root Caries

Root caries is decay on the root surface of the tooth. Root surfaces of teeth are composed of dentin, a much softer material than enamel. The caries process on the roots of teeth is similar to that of the enamel. However, dentin is less mineralized and softer than enamel and is therefore more vulnerable to decay. Fluoride-containing toothpastes, like 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste, are considered part of the primary protection from root caries and are also a viable treatment option for those with early stages of the disease process.[11]

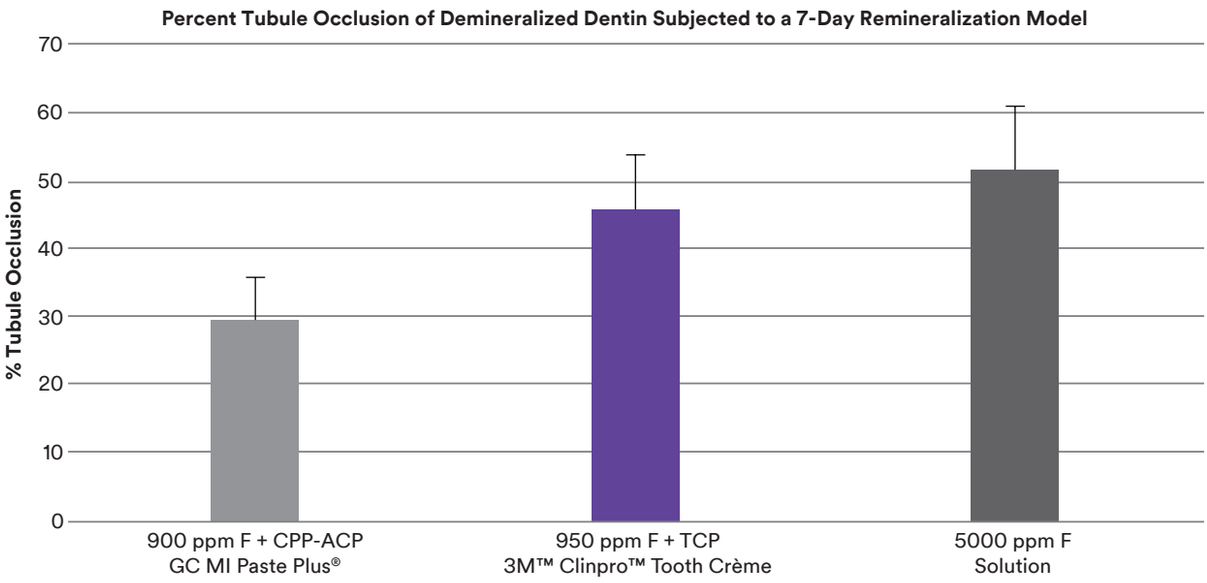
Dentin Tubule Occlusion

Methodology

Subsurface enamel lesions and demineralized dentin specimens were prepared and divided into the following treatment groups: GC MI Paste Plus®; Clinpro Tooth Crème toothpaste with TCP; or 1.1% sodium fluoride (5000 ppm fluoride ion) toothpaste. Enamel specimens were subjected to 4-minute treatments followed by a 3-hour acid challenge, administered twice daily, with immersions in artificial saliva (pH 7) after each acid challenge and distilled water rinsing between each event. After 28 days, samples were cross-sectioned and assessed using polarized light microscopy. Next, demineralized dentin specimens were subjected to 2-minute brushing periods (20,000 strokes per minute by electric toothbrush), twice per day, for 7 days, and immersed in artificial saliva in between these events. Tubule occlusion was then determined using images collected by scanning electron microscopy.

Results

Regular use of Clinpro Tooth Crème toothpaste occludes exposed dentin tubules similarly to prescription-strength fluoride toothpastes and better than GC MI Paste Plus®.[12]



Source: Prabhakar and Manojkumar

Fluoride Recharge

Many dental restorative and sealant materials contain and release fluoride. This is considered to be an advantage in protecting against a recurrence of caries after dental treatment is complete. Fluoride release from such materials is initially high but declines naturally with time.[13]

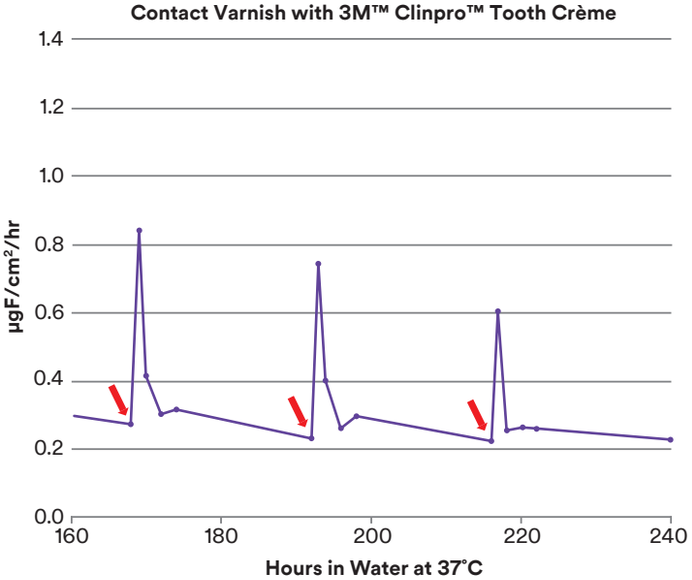
Methodology

Fluoride release of light-cured dental materials was measured before and after treatments with 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste. Release was measured at 1, 2, 3, 6 and 7 days after immersion using a fluoride-selective electrode. All samples were depleted of their "initial burst" of fluoride, after which samples entered a steady-state release phase. Toothpaste treatments (1:3 paste:H2O, 2 min) were applied at 7, 8 and 9 days and measured at 1, 2, 4, 6 and 24 hours after each treatment.

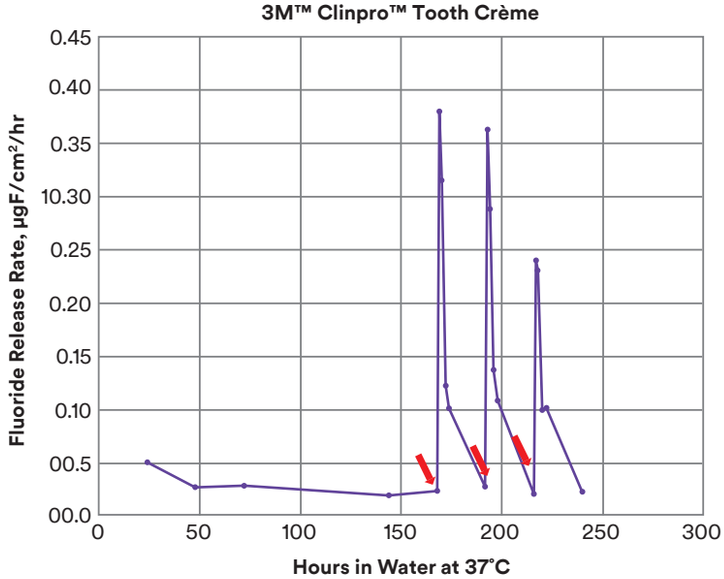
Results

In vitro testing demonstrates that fluoride-releasing materials can absorb and continue to rerelease fluoride after brushing with Clinpro Tooth Crème toothpaste. This ability to recharge dental materials with fluoride has been recognized in glass ionomers and resin-based sealant material.

Fluoride Release Rate of 3M™ Vanish™ XT Extended Contact Varnish with 3M™ Clinpro™ Tooth Crème



Fluoride Release Rate of 3M™ Clinpro™ Sealant with 3M™ Clinpro™ Tooth Crème



Source: 3M internal data

Extrinsic Stain Removal

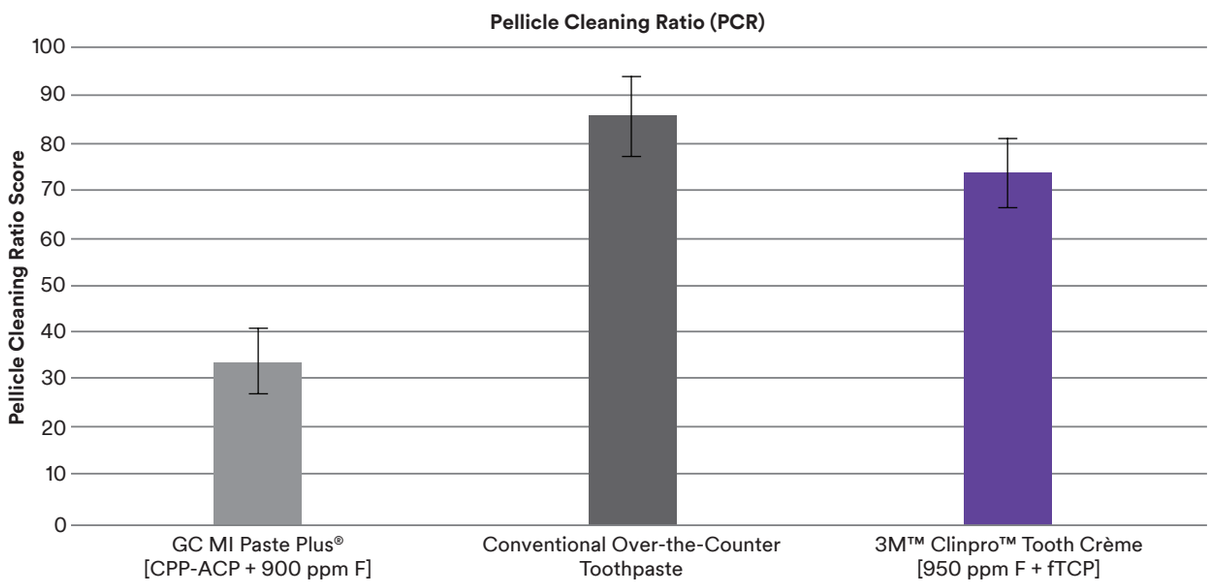
The cleaning efficiency of fluoride-containing toothpastes is determined using the Pellicle Cleaning Ratio (PCR) test. This *in vitro* test evaluates the ability of a fluoride-containing preparation to remove stained pellicle compared to that of a reference standard, calcium pyrophosphate. Higher PCR scores are reflective of better cleaning and whitening. In this experiment, over-the-counter toothpastes typically exhibit PCR scores between 65 and 115.[14]

Methodology

Specimens of enamel were prepared from bovine teeth. The specimens were stained by alternatively submerging and air-drying in a solution of soy broth, tea, coffee, mucin and *Sarcina lutea* for a period of 4 days. Following staining, the color of each specimen was measured using a spectrophotometer. Stained specimens were placed on a V-8 cross-brushing machine equipped with soft-bristled toothbrushes. One hundred fifty grams of force was applied to the toothbrushes. Specimens were brushed with slurries (25 grams of fluoride-containing preparation and 40 grams of deionized water) for a total of 800 strokes. One slurry contained 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste, while the others contained GC MI Paste Plus® or a conventional 1100 ppm fluoride toothpaste. Following brushing, the color of each specimen was measured again. The change in color observed for each slurry was compared to that observed for a reference standard of calcium pyrophosphate to determine the PCR score.

Results

Clinpro Tooth Crème toothpaste exhibited a PCR value of 73.9, which indicates effective stain removal. This value is statistically greater than the 33.8 PCR value achieved with GC MI Paste Plus®. Clinpro Tooth Crème toothpaste effectively cleans and whitens teeth.



Source: 3M internal data

Abrasivity

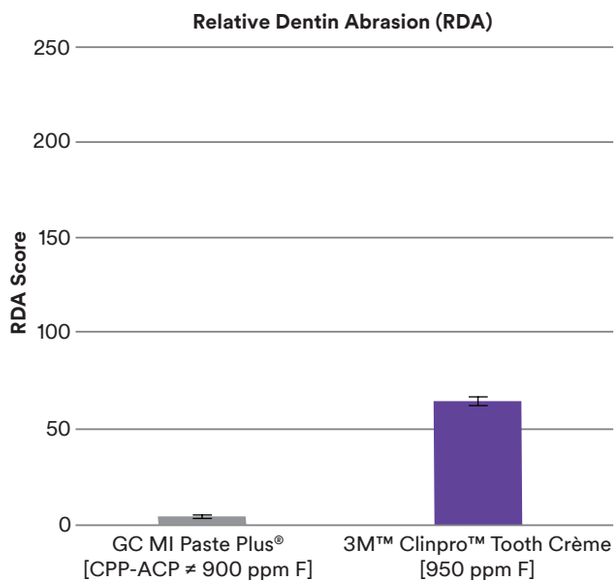
Toothpastes need to strike a balance between effective cleaning and abrasivity. Toothpastes that are highly abrasive can damage enamel and dentin over time. ISO 11609 Dentistry—Toothpastes—Requirements, Test Methods and Marking contains an abrasivity requirement and provides appropriate test methods for determining abrasivity. Two tests, relative dentin abrasion (RDA) and relative enamel abrasion (REA), were performed to determine if the abrasive system used in this formulation is safe for twice-daily, unsupervised toothbrushing.

Methodology

The RDA and REA tests are similar. Irradiated dentin or enamel was brushed with slurries (25 grams of fluoride-containing preparation with 40 grams of deionized water). One slurry contained Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste, while another contained GC MI Paste Plus® (900 ppm F-). Abrasivity was reported relative to a reference standard abrasive, calcium pyrophosphate. When evaluating dentin, the test formulation must not exceed 2.5 times that of the reference standard abrasive (that is assigned a value of 100); when evaluating enamel, the test formulation must not exceed 4 times that of the reference standard abrasive (that is assigned a value of 10). Because dentin is considered approximately tenfold more susceptible to abrasion than enamel (the reason for the assignment of 100 and 10 for the reference standard), dentin abrasivity is often viewed as a more appropriate measure of abrasivity to ensure the preparation is not overly aggressive.

Results

The RDA value observed for 3M™ Clinpro™ Tooth Crème 0.21% Sodium Fluoride Anti-Cavity Toothpaste was 59.58, well under the limit of 250. The REA value for Clinpro Tooth Crème toothpaste was 3.95, well under the limit of 40. Clinpro Tooth Crème toothpaste provides gentle, effective cleaning of enamel and exposed dentin.



Source: 3M internal data

Sources

1. Frenkel, E. S., & Ribbeck, K. (2015). Salivary Mucins Protect Surfaces from Colonization by Cariogenic Bacteria. Applied and Environmental Microbiology. *Applied and Environmental Microbiology, 81*(1), 332–338. doi:10.1128/aem.02573-14

2. Neel, E. A. A., Aljabo, A., Strange, A., Ibrahim, S., Coathup, M., Young, A. M., Bozec, L., & Mudera, V. (2016). Demineralization–remineralization dynamics in teeth and bone. *International Journal of Nanomedicine, 11*, 4743–4763. doi:10.2147/ijn.s107624

3. Young, D. A., Nový, B. B., Zeller, G. G., Hale, R., Hart, T. C., & Truelove, E. L.; American Dental Association Council on Scientific Affairs. (2015). The American Dental Association Caries Classification System for Clinical Practice: A report of the American Dental Association Council on Scientific Affairs. *The Journal of the American Dental Association, 146*(2), 79–86. doi:10.1016/j.adaj.2014.11.018

4. Mravak-Stipetić, M. (2012). Xerostomia—diagnostics and treatment. *Rad 514 Medical Sciences, 38*, 69–91.

5. Rošin-Grget, K., Peroš, K., & Šutej, I. (2013). The cariostatic mechanisms of fluoride. *Acta Medica Academica, 42*(2), 179–188. doi:10.5644/ama2006-124.85

6. Center for Scientific Information, ADA Science Institute. (2017). Fluoride: Topical and Systemic Supplements. Retrieved February 18, 2019, from https://www.ada.org/en/member-center/oral-health-topics/fluoride-topical-and-systemic-supplements

7. O'Mullane, D. M., Baez, R. J., Jones S., Lennon, M. A., Petersen, P. E., Rugg-Gunn, A. J., Whelton, H., & Whitford, G. M. (2016). Fluoride and Oral Health. *Community Dental Health, 33*(2), 69–99.

8. Roopa, K. B., Pathak, S., Poornima, P., & Neena, I. E. (2015). White spot lesions: A literature review. *Journal of Pediatric Dentistry, 3*(1), 1–7. doi:10.4103/2321-6646.151839

9. Bolin, K. A., Karlinsey, R. L., Mackey, A., Bitouni, A., Jones, D., & Skur, P. (2013). In situ Evaluation of 950 and 1100 ppm F Dentifrices. [Special issue A]. *Journal of Dental Research, 92*, 2030.

10. Limvirat, P., Nakornchai, S., Surarit, R., & Anuwongnukroh, N. (2012). Post-orthodontic White Lesion After Treated With Tri-calcium Phosphate Toothpaste. [Special issue C]. *Journal of Dental Research, 91*, 151627. (Southeast Asian Division)

11. Tan, H., Richards, L., Walsh, T., Worthington, H. V., Clarkson, J. E., Wang, L., & Mattar de Amoedo Campos Velo, M. (2017). Interventions for managing root caries. *Cochrane Database of Systematic Reviews*, (8). doi:10.1002/14651858.cd012750

12. Prabhakar, A. R., Manojkumar, A. J., & Basappa, N. (2013). In vitro remineralization of enamel subsurface lesions and assessment of dentine tubule occlusion from NaF dentifrices with and without calcium. *Journal of Indian Society of Pedodontics and Preventive Dentistry, 31*(1), 29–35. doi:10.4103/0970-4388.112403

13. Dasgupta, S., Saraswathi, M. V., Somayaji, K., Pentapati, K. C., & Shetty, P. (2018). Comparative evaluation of fluoride release and recharge potential of novel and traditional fluoride-releasing restorative materials: An in vitro study. *Journal of Conservative Dentistry, 21*(6), 622–626. doi:10.4103/jcd.jcd_338_18

14. White, D. J., & Kozak, K. M. (2002, March). *The pellicle cleaning ratio effects of multi-benefit dentifrices [Abstract]*. Research presented at the 80th General Session of the International Association for Dental Research, San Diego, CA.

www.3M.com

3M Oral Care
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Phone 1-800-634-2249
Web 3M.com/dental

3M Deutschland GmbH
Location Seefeld
3M ESPE • ESPE Platz
82229 Seefeld • Germany
Info3MESPE@mmm.com
www.3MESPE.com